PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P3504A	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/01403	International filing date *(day/month/year)* 10.03.2003	Priority date *(day/month/year)* 08.03.2002
International Patent Classification (IPC) or both national classification and IPC A61M16/00, A61M16/00		
Applicant KAERYS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06.10.2003	03.06.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Valfort, C Telephone No. +49 89 2399-2352

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/01403

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-20 filed with telefax on 27.04.2004

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1,2,4-20
	No:	Claims	3
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

   see separate sheet

D1: EP-A-1177810
D2: EP-A-1166813
D3: EP-A-0821976
D4: WO-A-9857691
D5: WO-A-9211054
D6: WO-A-02053217

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. D1 which is considered as the closest prior art discloses an apparatus to assist patient ventilation (see fig.2), from which the subject-matter of claim 3 differs in that the second pressure sensor used to determine the flow at the patient mask is not placed at the output of the blower, but as explained paragraph 44 and 45 of D1 on each sides of an organe which is provided in order to create a pressure drop measured by the two pressure sensors and in that in D1 no mention is made that the control unit comprises offset compensation means for compensating the possible difference of gauging between the two pressure sensors. Nevertheless, in D1 the type of the said organe for providing the pressure drop is not explicitly mentioned, it is clear for the skilled person that said can be a diaphragm, a venturi or any other suitable part creating a known pressure drop. The flow being then derivable from the two pressure values and the Bernouilli law. Moreover it is well known from the skilled person that when two pressure sensors are used in such a measuring system, there is a need to calibrate the two sensors in order to insure proper calculation, a traditional way of doing it is to use offset compensation means. Therefore, the subject-matter of claim 3 does not appear to imply an inventive step (Article 33(3) PCT) in view of document D1 taken with the general knowledge of a skilled person working in fluid mechanics.

2. The subject-matter of claim 1 differs from the device of D1 in that the second pressure sensor is placed at the output of the blower and in that the control unit is devised to calculate the airflow resistance Kt from a tube to be connected to the apparatus from the pressures measured at the extremity of the tube and at the output of the blower and the coefficient Ks (airflow resistance known) of a shell with a traversing hole to be connected at the extremity of the tube, and the control unit is able to calculate the airflow through the tube.

3. The problem to be solved by the invention can therefore be regarded as how to provide an alternative to the flowmeter system of D1.

4. The available documents do not hint at the control unit according to claim 1. D2 which discloses another calibration technique which needs both a flow and pressure sensor leads away from the control unit according to claim 1. (Nevertheless, D6, see point 3. may be of relevance at a latter stage).

5. Claims 2,4-18 (when dependent on claim 4 but not 3), are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

6. The closest prior art concerning process claims 19 and 20, appears to be document D2, which teaches a breath-hold technique, needing a pressure and flow sensor in order to calibrate and compensate for the breathing tube resistance, using a pressure drop over the time of the breath-hold. Said document appears to lead rather away from the technique used in claims 19 and 20, with the shell having a calibrated hole. Therefore, the subject-matter of claims 19 and 20 appears to imply an inventive step (Article 33(3) PCT).

7. Certain published documents (Rule 70.10)

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO02053217	11/07/2002	24/12/2001	29/12/2000

The document above may be of relevance later in the procedure (see citations in the international search report).

CLAIMS

1. An apparatus (1) to assist a patient respiration by delivering air to a patient trough a mask, said mask being designed to be connected on one first extremity of a tube, said apparatus comprising :

- a control unit (2) to adjust the pressure delivered by the blower (4) of said apparatus,
- a first pressure sensor (6) for sensing the pressure PM at said first tube extremity and being connected to said control unit, and
- a second pressure sensor (8) for sensing the pressure PB at the air output of said blower and being connected to said control unit;

in order that, when a tube is connected to said mask and connected to said apparatus on its said second extremity, the air flowing from the apparatus to the mask, said control unit is able to calculate the airflow at said second extremity of the tube from said pressures PM and PB and from the airflow resistance coefficient K_T of said tube ;

wherein when a tube is connected between said apparatus (1) and a shell (10) with a traversing hole (12) having a known airflow resistance coefficient K_s, the air flowing from the apparatus to said shell, the measured pressures PM and PB are send to said control unit (2) which calculates the tube airflow resistance coefficient K_T from these measured pressures and from the said coefficient K_s.

2. The apparatus according to claim 1, wherein the control unit (2) comprises offset compensation means for compensating the possible difference of gauging between the two pressure sensors (6 and 8).

3. An apparatus (1) to assist a patient respiration by delivering air to a patient trough a mask, said mask being designed to be connected on one first extremity of a tube, said apparatus comprising :

- a control unit (2) to adjust the pressure delivered by the blower (4) of said apparatus,
- a first pressure sensor (6) for sensing the pressure PM at said first tube extremity and being connected to said control unit, and
- a second pressure sensor (8) for sensing the pressure PB at the air output of said blower and being connected to said control unit;

in order that, when a tube is connected to said mask and connected to said apparatus on its said second extremity, the air flowing from the apparatus to the mask, said control unit is able to calculate the airflow at said second extremity of the tube from said pressures PM and PB and from the airflow resistance coefficient K_T of said tube ;

wherein the control unit (2) comprises offset compensation means for compensating the possible difference of gauging between the two pressure sensors (6 and 8).

4. The apparatus according to claim 3, wherein when a tube is connected between said apparatus (1) and a shell (10) with a traversing hole (12) having a known airflow resistance coefficient K_s, the air flowing from the apparatus to said shell, the measured pressures PM and PB are send to said control unit (2) which calculates the tube airflow resistance coefficient K_T from these measured pressures and from the said coefficient K_s.

5. An apparatus (1) according to claim 2 to 4, wherein said offset compensation means comprise :

- a microprocessor (30)
- a digital to analog converter (32) connected to said microprocessor (30) in order to convert microprocessor's digital data in analog data,
- an analog subtractor (34) having inputs connected to the second pressure sensor (8), to the first pressure sensor (6), and to said digital to analog converter,

said microprocessor calculating, when the blower is not functioning, the difference between the two pressures measured by said first and second pressure sensors and then sending the

value C of this difference to said digital to analog converter, which converts said value C in analog data and drive it to said analog subtractor, which subtract the pressure PB measured by said second pressure sensor and said value C to the pressure PM measured by said second pressure sensor and send the corresponding result D to the microprocessor, which will modify the C value until said D result equals zero, said microprocessor capturing the C value when said D result equals zero, enabling the control unit to correct the difference of offsets between the pressure sensors.

6. An apparatus according to claim 5, further comprising an analog amplifier (36) connected to said analog subtractor (34) in order to amplify the signal corresponding to said D result and to send it to said microprocessor (30), thus enabling said microprocessor to have an accurate adjustment of said value C until said result D reaches the value zero.

7. An apparatus according to claim 6, further comprising analog to digital converters (42, 44 and 40) connected between the microprocessor (30) and the said first pressure sensor (6), between the microprocessor and the said second pressure sensor (8), and between the microprocessor and the said analog amplifier (36), so that the microprocessor is provided with only digital data.

8. The apparatus according to any one of the precedent claims, wherein when at least one filter (22) is placed at one tube's extremity, said control unit (2) is able to calculate the airflow at said second extremity of the tube (20) from these measured pressures PM and PB and from the airflow resistance coefficient K_T of said tube and from the airflow resistance coefficient K_F of said filter.

9. An apparatus according to any one of the precedent claims, wherein said control unit (2) comprises a non volatile memory in which the control unit stores, as a couple of values, the two pressures PM(J) and PB(J), measured at each said pressure sensors (6 and 8) when said control unit forces the blower to deliver a determined constant pressure I at one

of the two sensors (6 or 8), so that when at least two couples of pressures corresponding to two different said determined constant pressure I are stored, the control unit is able to calculate an average of said coefficient K_T.

10. The apparatus according to any one of the precedent claims, wherein said control unit (2) comprises an estimation module (100) connected to the means for detecting the patient's breathing parameters (110), in order that the estimation module is able to determine when the patient is inspiring or expiring and in response the pressure to apply to the patient's mask, so that the control unit adjust the pressure delivered by the blower.

11. The apparatus according to claim 10, wherein the control unit (2) comprises a non volatile memory (120) in which the clinician can enter clinical settings comprising at least the treatment pressure and possibly the pressure to apply according to the patient's breathing parameters, said estimation module (100) applying the pressure according to these clinical settings and to the patient's breathing parameters.

12. The apparatus according to claim 11, wherein the patient can enter patient settings (122) in said non volatile memory, said estimator applying the pressure according to these patient settings and to the patient's breathing parameters within bounds given by the clinician settings.

13. The apparatus according to any one of claim 10 to 12, in which the estimation module 100 is able to determine that an event (E_1, E_2 or E_3) occurs in patient's breathing thus enabling said control unit to adjust the tension to apply to the blower to adjust the pressure at patient's mask.

14. The apparatus according to any one of claim 10 to 13, wherein said means (6) for detecting the patient's breathing parameters enable the control unit (2) to compute the airflow at patient's mask (20), said comparator determining that an event (E_1, E_2 or E_3) is occurring with the airflow parameters or shape.

15. The apparatus according to claim 10 to 14, wherein said estimation module has an inspiration out put (102) where said estimation module set the mask pressure PM value during inspiration and wherein said estimation module has an expiration out put (102) where said estimation module set the mask pressure PM value during expiration, said control unit comprising a switch which is connected alternatively to the inspiration out put (102) or expiration out put (102) according to patient's breathing.

16. The apparatus according to claim 10 to 15, wherein the apparatus further comprise a starting mean which when actuated enables the estimation module (100) to determine if a breathing activity is detected, the estimator module sending the instruction to stop the blower if no activity is sensed after a given delay.

17. The apparatus according to any one of the previous claim, further comprising a Frequency Shift Keying (FSK) modulator 50 which transforms the binary data send by the apparatus sensors or elements in a modulation of the frequency of the tension applied on a voltage controlled current source 52, connected to the external power supply, so that the voltage controlled current source 52 transmit the modulation corresponding to the data, a FSK demodulator converting the voltage frequency modulation into binary data 61 and transmit to the elements, so that each sensor or module connected to the power source is able to receive or transmit information.

18. Set for calibrating a tube used in apparatus to assist patient's respiration comprising :

- an apparatus according to claim 1 to 6
- a shell (10) with a traversing hole (12) having a known airflow resistance coefficient K_s.

19. Process for calibrating a tube used in apparatus to assist patient's respiration by using the apparatus (1) according to any of claim 1 to 9, said process comprising :

- connecting a first tube's (20) extremity to the blower (4) of said apparatus,

- connecting said first pressure sensor (6) to measure the pressure PM at a second tube's extremity,
- connecting said second extremity to a shell (10) with a traversing hole (12) having a known airflow resistance coefficient K_S,
- switching the blower on,
- instructing said control unit (2) to measured the pressures on said first pressure sensor and on the second pressure sensor (8), which is measuring the pressure PB at the blower's apparatus outlet, and
- calculating the value of the tube airflow resistance coefficient K_t from these measured pressures PM and PB and from the said coefficient K_s.

20. Process for calibrating the tube used in apparatus to assist patient's respiration, and for calibrating the tube by using the apparatus (1) according to any of claim 1 to 9, said process comprising :
- connecting a first tube's (20) extremity to the blower (4) of said apparatus,
- connecting said first pressure sensor (6) to measure the pressure PM at a second tube's extremity,
- connecting said second extremity to a shell (10) with a traversing hole (12) having a known airflow resistance coefficient K_S,
- switching the blower on,
- fixing at a value I the pressure provided and measured on one pressure sensor,
- instructing said control unit (2) to measured the pressures on said first pressure sensor and on the second pressure sensor (8), which is measuring the pressure PB at the blower's apparatus outlet,
- storing these measures PM(J) and PB(J) as a couple of measures associated to said value I,
- repeating a number of time N the steps 5 to 6 of said process, said value I being different for each time, so that each couples of pressures is associated with one value I,

- calculating (20) on average of the airflow resistance coefficient K_T from these measured pressures PM and PB and from the said coefficient K_S.